

CLAIMS

We I claim:

~~A 3/5/46~~ 1. A pharmaceutical composition in solid form comprising bupropion hydrochloride and carboxyvinyl polymer in an effective stabilizing amount.

5 2. The composition of claim 1, in which the composition contains at least about 90% w/w of undegraded bupropion hydrochloride after storage for 2 weeks at 55°C.

3. The composition of claim 1, in which the composition contains at least about 90% w/w of undegraded bupropion hydrochloride after storage for 3 months at 40°C and 75% relative humidity.

4. A pharmaceutical composition according to claim 1, which comprises from about 0.5% to 30% by weight of carboxyvinyl polymer as stabilizer to inhibit the degradation of bupropion hydrochloride.

~~A 3/5/46~~ 5. A pharmaceutical composition according to claim 1, which comprises from about 5% to 30% by weight of carboxyvinyl polymer to provide drug release over a 15 period of from about 8 hours to about 24 hours.

6. A pharmaceutical composition according to claim 5, which comprises from about 5% to about 30% by weight of the carboxyvinyl polymer.

7. A pharmaceutical composition according to claim 5, which comprises from about 8% to 28% by weight of carboxyvinyl polymer.

20 8. A pharmaceutical composition according to claim 5, which comprises from about 10% to about 28% by weight of carboxyvinyl polymer.

9. A method of stabilizing bupropion hydrochloride in a pharmaceutical composition according to claim 1, wherein said method comprises mixing bupropion hydrochloride with suitable pharmaceutical excipients and carboxyvinyl polymer and granulating with purified water.

10. A pharmaceutical composition according to claim 1 further comprising a pharmaceutical excipient selected from the group consisting of lactose, magnesium stearate and microcrystalline cellulose.

11. A pharmaceutical composition according to claim 10, wherein the pharmaceutical excipient is microcrystalline cellulose.

12. A sustained release tablet comprising bupropion hydrochloride, carboxyvinyl polymer and lactose.

13. A sustained release tablet comprising bupropion hydrochloride, carboxyvinyl polymer and microcrystalline cellulose.

14. A sustained release tablet according to claim 12, wherein the mean release of bupropion hydrochloride is one of about between 30% and 45% in 1 hour, about between 60% and 80% in 4 hours, and not less than 85% in 7 hours when tested in distilled water using the United States Pharmacopoeia paddle dissolution method at a rotational speed of 50 rpm.

15. A sustained release tablet according to claim 13, wherein the mean release of bupropion hydrochloride is one of about between 30% and 45% in 1 hour, about between 60% and 80% in 4 hours, and not less than 85% in 7 hours when tested in distilled

water using the United States Pharmacopoeia paddle dissolution method at a rotational speed of 50 rpm.

16. A sustained release tablet according to claim 12, wherein the mean release of bupropion hydrochloride is one of about between 10% and 25% in 1 hour, about between 30% and 60% in 8 hours, and not less than 65% in 12 hours when tested in distilled water using the United States Pharmacopoeia paddle dissolution method at a rotational speed of 50 rpm.

17. A sustained release tablet according to claim 13, wherein the mean release of bupropion hydrochloride is one of about between 10% and 25% in 1 hour, about between 30% and 60% in 8 hours, and not less than 65% in 12 hours when tested in distilled water using the United States Pharmacopoeia paddle dissolution method at a rotational speed of 50 rpm.